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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,916	02/16/1999	SMITA K. NAIR	1579-312	8645

7590 04/24/2002

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/171,916

Applicant(s)

NAIR ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/6/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 25-27, 29-41 and 44-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-59 is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-15, 17, 18, 25-27 and 29-41 is/are rejected.
- 7) ☒ Claim(s) 10-12, 16 and 44-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-9, 13, 25-27 and 29-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,306,388 (hereafter the '388 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method for producing RNA loaded antigen presenting cells (APCs). The instant claims differ from those in the '388 patent in that the instant claims recite that the APCs resulting from the process present on their surface a tumor or pathogen derived antigenic epitope which induces T cell proliferation. However, this does not distinguish the claims from those in the '388 patent because the method for producing APCs recited in the '388 patent is designed to produce APCs which present tumor (or pathogen) antigenic epitopes on their surface. The purpose of using APCs to present antigens to the host immune system is precisely to elicit T cell proliferation and

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induce cellular immunity. Therefore, the ordinary skilled artisan would have been motivated to use the method for producing RNA loaded APCs which express tumor or pathogen derived antigens on their surface as claimed in the '388 patent in order to generate the same method for producing the same APCs with the expectation that the APCs so generated would express a tumor or pathogen derived antigenic epitope capable of inducing T cell proliferation because the method recited in the '388 patent is designed to produce just such an epitope presenting APC. It would have been obvious for the ordinary skilled artisan to do this because the method for producing APCs recited in the claims of the '388 patent is designed to produce APCs which present tumor or pathogen epitopes which can induce T cell proliferation. Given the teachings of the claims in the '388 patent and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Also, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '388 patent, then two different assignees would hold a patent to the claimed methods of making APCs and thus improperly there would be possible harassment by multiple assignees.

3. Claims 1-9, 13-15, 17, 18, 25-27 and 29-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17, 19 and 27-38 of copending Application No. 09/875,264 (hereafter the '264 application). Although

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the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same methods of producing RNA loaded APCs, methods of treating patients having tumors and methods of producing cytotoxic T lymphocytes (CTLs). The rationale underlying the rejection of claims reading on methods of making APCs is identical to that in the above obviousness type double patenting rejection of claims 1-9, 13, 25-27 and 29-40 over the '388 patent. The instant claims reciting methods of making CTLs or treating patients suffering from tumors are the same as those recited in the '264 application except that they recite the use of the APCs which are obvious over the APCs made by the process claims of the '264 application. Therefore, one of ordinary skill in the art would have been motivated to use the APCs recited in the '264 application to generate the instant APCs and use them in the same methodologies (i.e. the claimed methods of making CTLs, etc.) as recited in the '264 claims. It would have been obvious for the ordinary skilled artisan to do this because the '264 application recites the same methodologies as instantly claimed and because the methodologies recite use of APCs which are not patentably distinct from the APCs generated in the '264 claims. Given the teachings of the claims in the '264 application and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 51-59 are allowed.

Claims 10-12, 16 and 44-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
April 21, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo